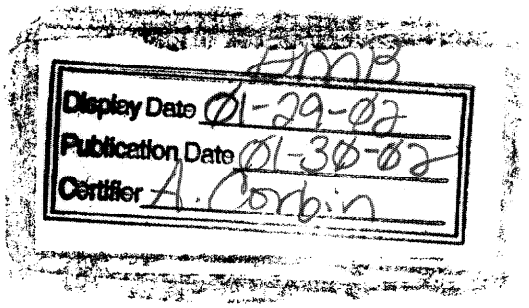


DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 98D–0016]

Withdrawal of Guidance Document on Professional Flexible Labeling of Antimicrobial Drugs

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is withdrawing a guidance for industry (#66) entitled "Professional Flexible Labeling of Antimicrobial Drugs." This guidance, which was issued in August 1998, is being withdrawn because it does not represent current agency thinking on the development of professional flexible labeling for therapeutic veterinary prescription antimicrobial drugs. The agency intends to develop a new document on this topic.

DATES: Submit written or electronic comments at any time.

ADDRESSES: Submit written comments to the Dockets Management Branch (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit electronic comments to http://www.fda.gov/dockets/ecomments. Comments should be identified with the full title of the guidance and the docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Andrew J. Beaulieu, Center for Veterinary Medicine (HFV–1), Food and Drug Administration, 7519 Standish Pl., Rockville, MD 20851, 301–827–2954.

SUPPLEMENTARY INFORMATION:

cv0197

NWL 1

I. Background

FDA is withdrawing a guidance for industry (#66) entitled "Professional Flexible Labeling of Antimicrobial Drugs." This guidance addresses the development of professional flexible labeling for prescription therapeutic antimicrobial new animal drugs. This guidance is being withdrawn because the agency now believes that the "broad indication" that was described in the guidance, particularly the very broad indication used as an example, is not consistent with the kind of database that typically can be generated to support an antimicrobial new animal drug approval. In the **Federal Register** of July 28, 1999 (64 FR 40746), the agency revised its definition of "substantial evidence" in the animal drug regulations (21 CFR 514.4). In light of that definition and experience regarding the manner in which products are being advertised or otherwise promoted for use under the "broad indication" provision of the guidance, FDA is withdrawing this guidance. The guidance no longer reflects the agency's current thinking on how sponsors can provide substantial evidence of effectiveness for all of the conditions that could fall within a "broad" (or "collective") indication on the label of a prescription therapeutic antimicrobial new animal drug.

The agency intends to develop a new guidance on this issue and will publish it as a level 1 draft guidance in accordance with the agency's good guidance practices in 21 CFR 10.115. The focus of the revisions will be the "Indications" and "Microbiology" sections of the guidance. The guidance revisions will more clearly set out the basis for the "Indication" section as "substantial evidence of effectiveness". In the interim, sponsors of antimicrobial products should consult with the Center for Veterinary Medicine (CVM) at FDA for more detailed information regarding acceptable content for the "Indications" and "Microbiology" sections of the labeling. In general, CVM encourages sponsors to discuss all aspects of product development through presubmission conferences and other meetings with CVM.

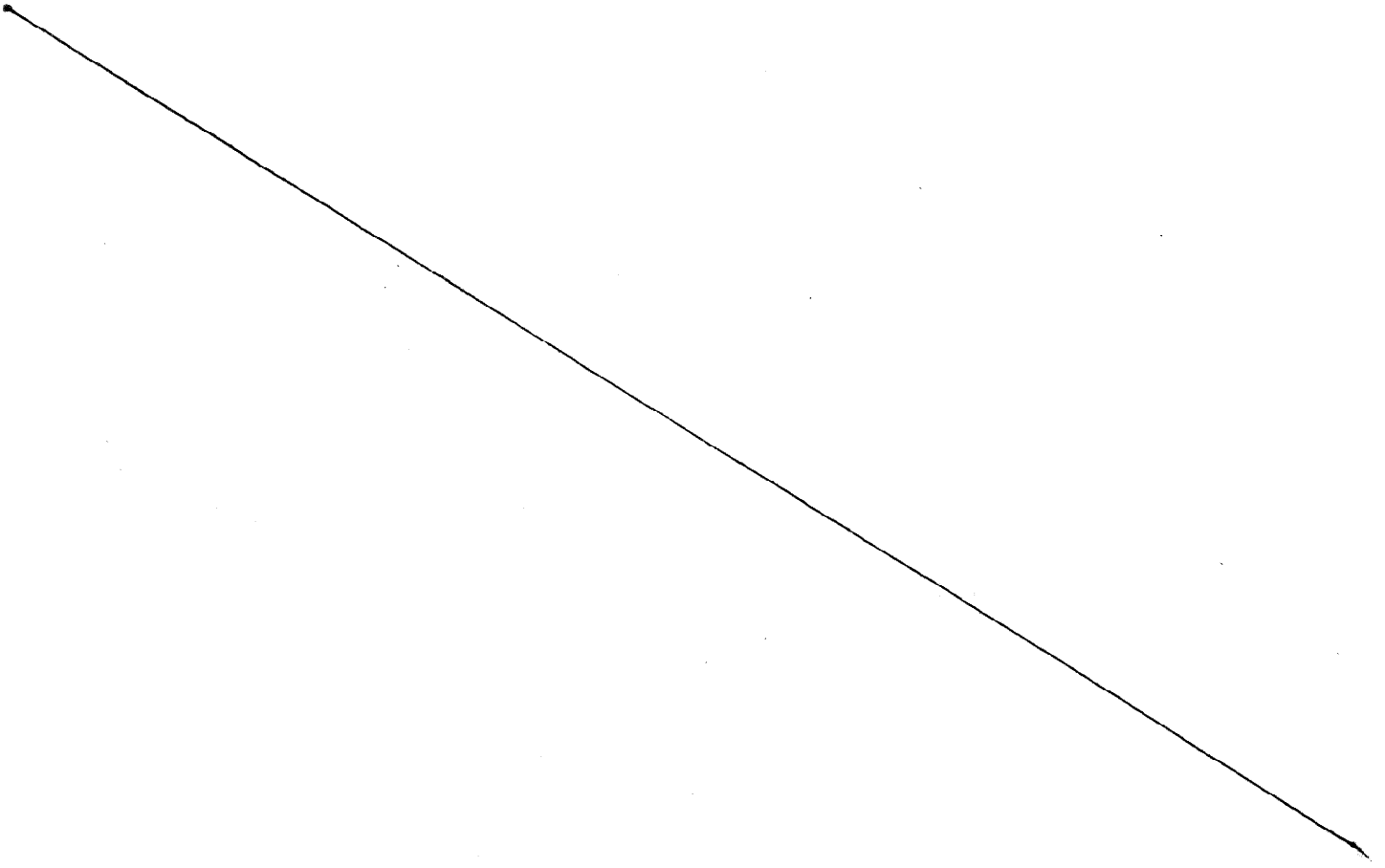
II. Significance of Guidance

This information is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). It does not create or confer any rights for or on any person and does not operate to bind FDA or the public.

III. Comments

The agency welcomes comments on its efforts to review existing guidances related to the development of new animal drug products and revise, reformat, or withdraw them, as appropriate.

Interested persons may submit written or electronic comments on agency guidance documents to the Dockets Management Branch (address above) at any time. Two copies of any written comments are to be submitted, except that individuals may submit one copy. Comments are to



be identified with the docket number found in brackets in the heading of this document. A copy of received comments is available for public examination in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

Dated: 1/23/02

January 23, 2002.

Margaret M. Dotzel,
Associate Commissioner for Policy.

[FR Doc. 02–????? Filed ??–??–02; 8:45 am]

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